



K-020502
MAY 01 2002

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: February 2002

Device Name:

- Trade Name – *Solo Ortho 3*
- Common Name – Orthodontic Bonding Primer
- Classification Name – Bracket Adhesive Resin and Tooth Conditioner, per 21 CFR § 872.3750

Devices for Which Substantial Equivalence is Claimed:

- Ormco Corporation, *Solo Ortho 2*

Device Description:

The device is a one-bottle, universal primer for labial and lingual bonding of ceramic or metal brackets. *Solo Ortho 3* can be used with either chemical or light cured adhesive systems.

Intended Use of the Device:

The intended use of *Solo Ortho 3* is as an enhancing primer for labial and lingual orthodontic bonding.

Substantial Equivalence:

Solo Ortho 3 is substantially equivalent to other legally marketed devices in the United States. *Solo Ortho 3* functions in a manner identical to and is intended for the same use as the product *Solo Ortho 2* cleared for marketing for Ormco Corporation.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 01 2002

Ms. Colleen Boswell
Director, Corporation Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K020502

Trade/Device Name: Solo Ortho 3
Regulation Number: 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: February 11, 2002
Received: February 14, 2002

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

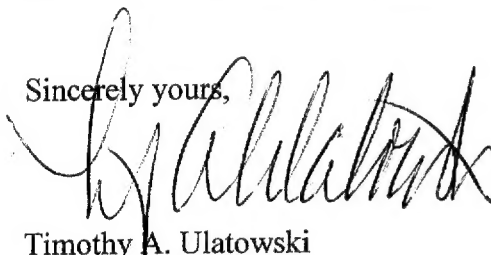
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I

Indications for Use Statement

Ver/ 3 - 4/24/96

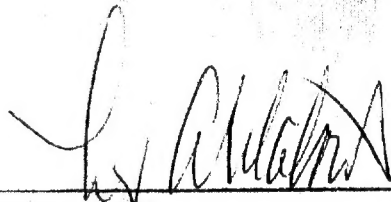
Applicant: Ormco Corporation

510(k) Number (if known): K 0 2 0 5 0 2

Device Name: Solo Ortho 3

Indications For Use:

Solo Ortho 3 is designed to be used as an enhancing primer for labial and lingual orthodontic bonding.



(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K020502

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)